IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Plaintiffs, v. LUPIN LIMITED AND LUPIN PHARMACEUTICALS, INC., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs"), by way of Complaint against Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. ("Lupin Inc.") (collectively, "Lupin"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Reissue Patent No. RE48,059 ("the RE'059 patent"), arising under the United States patent laws, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Lupin's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to engage in the commercial manufacture, use, importation, offer for sale or sale of generic pharmaceutical products before the expiration of the RE'059 patent.

THE PARTIES

2. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

3. Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Otsuka has granted Lundbeck an exclusive license to the RE'059 patent.

4. Otsuka and Lundbeck are engaged in the business of researching, developing and bringing to market innovative pharmaceutical products.

5. Upon information and belief, Lupin Limited is a corporation organized under the laws of India and its principal place of business is located at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India.

6. Upon information and belief, Lupin Inc. is a corporation organized under the laws of Delaware and its principal place of business is located at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, MD 21202. Upon information and belief, Lupin Inc. is a wholly owned subsidiary of Lupin Limited.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Lupin Limited. Upon information and belief, Lupin Limited is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Lupin Limited directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Lupin Limited purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Lupin's generic products.

9. Upon information and belief, Lupin Limited admits it is the "3rd largest [pharmaceutical company] in the U.S." by prescriptions. Lupin Limited, Investor Presentation Q4

FY2020 11 (May 29, 2020). Upon information and belief, Lupin Limited admits it has filed "430 US ANDAs," has received 272 approvals and has "43 pending US First to Files." *Id.* Upon information and belief, Lupin Limited further admits that "Lupin's Generic Pharmaceutical Research team has demonstrated a stellar performance with a record number of ANDA filings in the US[.]" https://www.lupin.com/research/generic-pharmaceutical-and-api-research (accessed Sept. 25, 2020).

10. Upon information and belief, Lupin Limited is the holder of FDA Drug Master File No. 33421 for brexpiprazole.

11. This Court has personal jurisdiction over Lupin Inc. Upon information and belief, Lupin Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Lupin Inc. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Lupin Inc. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Lupin's generic products.

12. Upon information and belief, Lupin Inc. admits it "has a strong and well-established generic presence in the United States, having entered the U.S. market in 2003 and maintaining a competitive edge in the list of top 5 generic pharmaceutical companies by prescriptions dispensed since 2010." https://www.lupin.com/US/about-us (accessed Sept. 25, 2020). Upon information and belief, Lupin Inc. admits it has "received more than 250 FDA approvals and market[s] a total of 180 generic products" in the United States. https://www.lupin.com/US/generics (accessed Sept. 25, 2020).

13. Upon information and belief, Lupin Inc. has an active pharmacy wholesale license

in the state of Delaware with the license number A4-0002387 and an active controlled substances distributor/manufacturer license in the state of Delaware with the license number DM-0012065.

14. Upon information and belief, Lupin Limited and Lupin Inc. hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

15. Upon information and belief, Lupin Limited admits that sales in the United States make up 38% of Lupin Limited's global revenue. https://www.lupin.com/our-world/corporate-overview (accessed Sept. 25, 2020). Upon information and belief, Lupin Limited further admits Lupin Inc. is its "U.S. marketing arm" and "is dedicated to delivering superior quality . . . generic medicines trusted by healthcare professionals and patients across the region." https://www.lupin.com/our-business/global-research-and-manufacturing-facilities/usa (Sept. 25, 2020).

16. Upon information and belief, Lupin Inc. admits it is "vertically integrated, from process development of the API to the submission of dossiers for finished dosages." https://www.lupin.com/US/generics (accessed Sept. 25, 2020). Upon information and belief, Lupin Inc. admits it operates as part of a "globally integrated network of 18 manufacturing facilities. [Lupin's] world class facilities are built to manufacture and deliver a wide range of finished products to the U.S. market. All facilities are committed to compliance with quality, safety and environmental standards." *Id.*

17. Lupin's ANDA filing regarding the RE'059 patent relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Lupin's intent to market and sell Lupin's generic products in this judicial district.

18. Lupin has taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—which, upon information and belief, will be purposefully directed at the District of Delaware and elsewhere throughout the United States. Upon information and belief, Lupin intends to direct sales of its generic drugs in this judicial district, among other places, once Lupin receives the requested FDA approval to market its generic products. Upon information and belief, Lupin will engage in marketing of its proposed generic products in Delaware upon approval of its ANDA.

19. Upon information and belief, Lupin has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 213512.

20. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Lupin Limited is incorporated in India and may be sued in any judicial district.

21. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Lupin Inc. is incorporated in the state of Delaware.

FACTUAL BACKGROUND

The NDA

22. Otsuka is the holder of New Drug Application ("NDA") No. 205422 for REXULTI® (brexpiprazole) Tablets in 0.25, 0.5, 1, 2, 3 and 4 mg dosage forms ("REXULTI® Tablets").

23. The FDA approved NDA No. 205422 on July 10, 2015.

24. REXULTI® Tablets are prescription drugs approved for the adjunctive treatment of major depressive disorder and the treatment of schizophrenia. Brexpiprazole is the active ingredient in REXULTI® Tablets.

The Patent In Suit

25. The United States Patent and Trademark Office ("the PTO") issued U.S. Patent No. 7,888,362 ("the '362 patent") on February 15, 2011, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders."

26. The PTO reissued the '362 patent as the RE'059 patent on June 23, 2020. A true and correct copy of the RE'059 patent is attached hereto as Exhibit A.

27. As the reissue of the '362 patent, Otsuka is the owner of the RE'059 patent through assignment as recorded by the PTO for the '362 patent at Reel 048501, Frame 0122; Reel 021939, Frame 0746 and Reel 048501, Frame 0166.

28. Pursuant to 35 U.S.C. § 251, the RE'059 patent issued for the unexpired term of the '362 patent, which would have expired on April 12, 2026, by virtue of a terminal disclaimer filed in the PTO that disclaimed 317 days of patent term adjustment granted to the '362 patent under 35 U.S.C. § 154(b). A true and correct copy of the terminal disclaimer is attached as Exhibit B.

29. Otsuka filed a Submission Pursuant to 37 C.F.R. § 1.765 for Patent Term Extension Application Under 35 U.S.C. § 156 and Response to Notice of Final Determination, requesting an extension under 35 U.S.C. § 156(c) of 986 days for the '362 patent. After the RE'059 patent issued, Otsuka filed a Petition Under 37 C.F.R. § 1.182 to Move Patent Term Extension Application from U.S. Patent No. 7,888,362 to RE 48,059. Accordingly, the RE'059 patent will expire on December 23, 2028, based on the 986 days of Patent Term Extension under 35 U.S.C. § 156(c).

30. The RE'059 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

The ANDA

31. Upon information and belief, Lupin filed ANDA No. 213512 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use, importation, offer for sale or sale in the United States of brexpiprazole tablets, 0.25, 0.5, 1, 2, 3 and 4 mg ("Lupin's generic products"), which are generic versions of Otsuka's REXULTI® (brexpiprazole) Tablets.

32. Otsuka received a letter sent by Lupin, dated September 5, 2019, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 213512 ("Lupin's September 5, 2019, First Notice Letter") pursuant to § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Lupin's September 5, 2019, Notice Letter notified Otsuka that Lupin had filed ANDA No. 213512, seeking approval to engage in the commercial manufacture, use, importation, offer for sale or sale of Lupin's generic products before the expiration of the '362 patent and U.S. Patent Nos. 8,349,840 ("the '840 patent"), 8,618,109 ("the '109 patent"), 9,839,637 ("the '637 patent") and 10,307,419 ("the '419 patent").

33. In response to Lupin's September 5, 2019, First Notice Letter, Plaintiffs previously filed a separate action in this Court against Lupin for patent infringement, which included counts of infringement of the '362, '840, '109, '637 and '419 patents. *See Otsuka Pharmaceutical Co., Ltd., et al. v. Lupin Limited, et al.*, C.A. No. 19-1988-LPS.

34. On June 23, 2020, the PTO issued the RE'059 patent as a reissue of the '362 patent. Plaintiffs timely notified the FDA and the RE'059 patent was listed in the Orange Book for REXULTI®.

35. Upon information and belief, ANDA No. 213512 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification"), alleging that claims of the RE'059 patent are invalid, unenforceable and/or would not be infringed by the commercial manufacture, use, sale, offer for sale and/or importation of Lupin's generic products.

36. Otsuka received a second letter sent by Lupin, dated August 12, 2020, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 213512 ("Lupin's August 12, 2020, Second Notice Letter") pursuant to § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Lupin's August 12, 2020, Second Notice Letter notified Otsuka that Lupin had filed ANDA No. 213512, seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation in the United States of Lupin's generic products before the expiration of the RE'059 patent.

37. Plaintiffs commenced this action within 45 days of receiving Lupin's August 12, 2020, Second Notice Letter.

COUNT I

(INFRINGEMENT OF THE RE'059 PATENT)

38. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

39. Upon information and belief, Lupin filed ANDA No. 213512 seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the RE'059 patent.

40. Upon information and belief, Lupin filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the RE'059 patent are invalid, unenforceable and/or not infringed.

41. Upon information and belief, in its ANDA No. 213512, Lupin has represented to the FDA that Lupin's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

42. Lupin has actual knowledge of Otsuka's RE'059 patent, as evidenced by Lupin's August 12, 2020, Second Notice Letter.

43. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed one or more claims of the RE'059 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213512, seeking approval to commercially manufacture, use, import, offer to sell or sell Lupin's generic products before the expiration date of the RE'059 patent.

44. Upon information and belief, if ANDA No. 213512 is approved, Lupin intends to and will offer to sell, sell and/or import in the United States Lupin's generic products.

45. Upon information and belief, if ANDA No. 213512 is approved, Lupin will infringe one or more claims of the RE'059 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Lupin's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213512 shall be no earlier than the expiration of the RE'059 patent and any additional periods of exclusivity.

46. Upon information and belief, Lupin's actions relating to Lupin's ANDA No. 213512 complained of herein were done by and for the benefit of Lupin.

47. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless this Court enjoins those activities.

48. Plaintiffs do not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Lupin has infringed at least one claim of the RE'059 patent through Lupin's submission of ANDA No. 213512 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the RE'059 patent;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Lupin's making, using, offering to sell, selling or importing of Lupin's generic products before the expiration of the RE'059 patent will infringe, actively induce infringement and/or contribute to the infringement of the RE'059 patent under 35 U.S.C. § 271(a), (b) and/or (c);

C. The issuance of an order that the effective date of any FDA approval of Lupin's generic products shall be no earlier than the expiration date of the RE'059 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining Lupin and all persons acting in concert with Lupin from commercially manufacturing, using, offering for sale or selling Lupin's generic products within the United States, or importing Lupin's generic products into the United States, until the expiration of the RE'059 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Lupin and all persons acting in concert with Lupin from seeking, obtaining or maintaining approval of the

ANDA until the expiration of the RE'059 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

G. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

H. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

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